REMARKS

The Official Action dated June 13, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 24 is cancelled. Claims 22-23 and 41-42 remain in the application. Claim 22 is amended to clarify the limitations therein and to recite that the growth hormone is human growth hormone. Claim 23 is amended to recite that the human growth hormone is recombinant human growth hormone and as to a matter of form. Finally, claim 42 is amended as to a matter of form and to change its dependency. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Figure 2 was objected to on the basis that the photograph and figure legends are of poor quality. Accordingly, Applicants submit herewith a new Figure 2 which is believed to overcome the objection set forth in the Official Action.

Claims 22-24 and 42 were rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification The Examiner asserted that while the specification is enabling for a method comprising administering to the patient recombinant human growth hormone (rhGH), it is not enabling for administering to the patient all kinds of growth hormone or functional derivatives thereof. The Examiner also asserted that as the growth hormone molecule can vary with the nature of the protein, its source and its binding

conditions, resulting in differences of immunological properties, the mere recitation of growth hormone and analogues thereof for "general treatment purposes" is insufficient to be enabling for all forms of growth hormone or analogues thereof.

This rejection is traversed with respect to present claims 22-23 and 41-42 and reconsideration is respectfully requested. More particularly, claim 22 is directed to a method for treating a patient having Metabolic Syndrome comprising Primary Insulin Resistance and abdominal/visceral obesity to decrease insulin resistance. The method comprises administering to said patient human growth hormone or functional analog thereof in an amount effective for decreasing insulin resistance of said patient.

Applicants submit that the recitation of "human growth hormone or a functional analog thereof" is fully enabled by the specification. Specifically, one skilled in the art recognizes that recombinant human Growth Hormone (rhGH) is produced by isolating the human Growth Hormone (hGH) gene and reproducing the hGH in high quantities by recombinant DNA techniques. Accordingly, rhGH is used interchangeably with natural human Growth Hormone for clinical use. Furthermore, one skilled in the art appreciates that an analog of human growth hormone or recombinant human growth hormone is encompassed by molecules which have human growth hormone activity. As defined in the specification at page 3, lines 19-20 an analog is "a substance having the same biological activity as described here and having at least 65% homology with natural occurring growth hormone".

A disclosure is enabling if, from the information set forth in the specification, coupled with information known in the art, one of ordinary skill in the art can make and use the invention without undue experimentation, *United States v. Teletronics, Inc.*, 8 USPQ2d 1217, 1224 (Fed. Cir. 1988). Moreover, every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification; rather, reasonable detail

must be provided in order to enable members of the public to understand and carry out the invention, *Genetec v. Novo Nordisc, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). Finally, a patent need not teach, and preferably omits, what is well known in the art, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). As the specification clearly defines "human growth hormone or a functional analog thereof", one skilled in the art will appreciate how to produce human growth hormone or a functional analog thereof for use in accordance with the present invention.

It is therefore submitted that present claims 22-23 and 41-42 are fully enabled by the specification, whereby the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

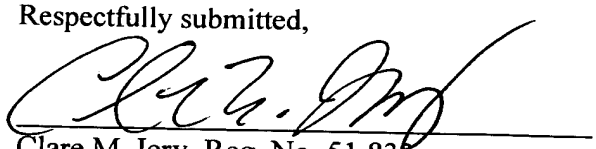
Claims 22-24 and 41-42 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. With respect to claims 22 and 23, the Examiner asserted that the recitation of "functional derivative thereof" (claim 22) and "functional analog thereof" (claim 23) is inconsistent. Applicants traverse the Examiner's position, however, to expedite prosecution of the application, claim 22 has been amended to recite "functional analog thereof". With respect to claim 24, the Examiner asserted that the claim is indefinite due to a typographical error. As claim 24 has been cancelled, Applicants submit that this rejection has been overcome.

It is therefore submitted that present claims 22-23 and 41-42 are fully defined by the specification, whereby the rejection under 35 U.S.C. §112, second paragraph, has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's objection and rejections under 35 U.S.C. §112, first and second paragraphs, and places the

present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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